

Institutional Biosafety Committee (IBC) Meeting Minutes

Institution:	Wake Forest University School of Medicine			
Meeting Date and Time:	February 18 th 2026			
Meeting Type:	Online via Microsoft Teams			
	Name	Role and Department	Attendance	
IBC Members Present:	Frank Marini, PhD	IBC Chair, WFIRM	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Anthony Blaeser, PhD	IBC Vice Chair Musculoskeletal Department	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Samuel Centanni, PhD	Voting Member, Translational Neuroscience	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Ji Hyun Kim, PhD	Voting Member, WFIRM	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Elizabeth Palavecino, MD	Voting Member, Pathology	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	David Ornelles, PhD	Voting Member, Microbiology and Immunology	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Marlena Westcott, PhD	Voting Member, Microbiology and Immunology	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Brian Strittmatter, PharmD, MSCR	Voting Member, Pharmacy Clinical Trial Services, Pharmacy Manager	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Patrick McNutt, PhD	Voting Member, WFIRM,	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Linda Metheny-Barlow, PhD	Voting Member, Radiation Oncology	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Swapn Das, PhD, MSc	Voting Member, IM. Endocrinology & Metabolism	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Caryn Gee Morse, MD, PhD	Voting Member, IM, Infectious Diseases	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Robert Hampson, PhD	Voting Member, WFIRM	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Farah Mougeot, PhD, MS	Voting Member, Translational Research – Oral Medicine	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Kimberly Woodward, MD, MPH	Voting Member, Pathology	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Paris Charilaou, MD, FACP	Voting Member, Gastroenterology and Hepatology	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
Yuming Jiang, MD, PhD	Voting Member, Radiation Oncology	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent	

	Dan Hurley	Local Non-Affiliated Community Member (Charlotte)	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Jeanette Bennett	Community Member (Charlotte)	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Kara Milton	Community Member (Winston Salem)	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Adam Bray	Community Member (Winston Salem)	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Christpher Ohl, MD	Voting Member, IM, Infectious Diseases (Ad- Hoc)	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Scott Gamble, DVM	Voting Member, Animal Expert	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Lisa Colvin	Voting Contact, IBC Administrator	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Emylee Pedersen	Voting Contact, IBC Administrator	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Jessica Baker	Voting Member, IACUC Representative	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Katy Heide	Voting Member, EHS, Environmental Compliance	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
Ex Officio W/O Vote				
	Suzy Mounsey	Animal Resources Program	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Gaye Hodges	Animal Resources Program	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Stephen Fisenne	WFU Representative	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Morgan Lawson	Environmental Health & Safety	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Jennifer Williams	Environmental Health & Safety	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Joseph Kim	AHWFB Teammate Health	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
Quorum:	Yes			
Call to Order:	12:32			
Conflicts of Interest:	None			
Review and Approval of Previous Meeting Minutes:	Motion to approve January minutes posed by Dr. Marini, Dr. Ornelles second.			
Review of Prior Meeting Business (if applicable):	None			
New IBC Registrations and Modifications for Review				
PI Name:	Atrash, Shebli			
Registration Number:	B26-CT-C-004			
Biosafety Protocol Title:	68284528MMY2012: A Phase 2 Multicohort Trial to Further Characterize the Efficacy and Safety of Ciltacabtagene Autoleucel (CARTITUDE-10)			

Project Overview:	if JNJ-68284528 (ciltacabtagene autoleucel [cilta-cel]) is safe and useful for treating patients with newly diagnosed multiple myeloma who are in their first line of therapy.
Applicable NIH Guidelines:	Section III-C-I
Agent Description: e.g. virulence, pathogenicity, environmental stability	██████████ antigen receptor (CAR) utilizing a ██████████ vector. The target antigen of the CAR is ██████████ which is expressed on malignant plasma cells.
Types of Manipulations:	Manipulations performed by the drug manufacturer
Source of nucleic (DNA/RNA) sequences: e.g. species	NA
Nature of nucleic acid sequences: e.g. structural gene, oncogene	██████████ gene expression
Host(s) and Vector(s):	Host: ██████████ Vector: ██████████
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	██████████
Risk Assessment Discussion Points:	None
Training:	Training provided by the sponsor
Occupational Health Review (if applicable):	None
Biosafety Level: Animal Biosafety Level:	BSL 2
IBC Vote:	Approved
New IBC Registrations and Modifications for Review	
PI Name:	Atrash, Shebli
Registration Number:	B26-CT-C/WS-005
Biosafety Protocol Title:	D8311C00001: A Phase III Open-label, Randomised, Multicentre Study Comparing AZD0120, a Dual-Targeting Autologous Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA and CD19, versus Standard Regimens in Participants with Relapsed Refractory Multiple Myeloma (DURGA-4) (ClinicalTrials.gov Identifier: NCT07391657)
Project Overview:	
Applicable NIH Guidelines:	Section III-C-I
Agent Description:	██████████ anti CD-19 and BCMA CARs using ██████████ vector system/

e.g. virulence, pathogenicity, environmental stability	
Types of Manipulations:	Manipulations performed by the drug manufacturer
Source of nucleic (DNA/RNA) sequences: e.g. species	NA
Nature of nucleic acid sequences: e.g. structural gene, oncogene	[REDACTED]
Host(s) and Vector(s):	Host: [REDACTED] Vector: [REDACTED]
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	Anti CD-19, and Anti BCMA
Risk Assessment Discussion Points:	None
Training:	Training provided by the sponsor
Occupational Health Review (if applicable):	None
Biosafety Level: Animal Biosafety Level:	2
IBC Vote:	Approved at BSL 2
New IBC Registrations and Modifications for Review	
PI Name:	Watabe, Konosuke
Registration Number:	B26-W-013
Biosafety Protocol Title:	Role of Alcohol in Promoting Cancer
Project Overview:	Evaluation of the pathological mechanisms of alcohol-related liver disease and cancer progression and testing efficacy of [REDACTED] in suppressing alcohol-related liver disease cancer progression.
Applicable NIH Guidelines:	Section III-E
Agent Description: e.g. virulence, pathogenicity, environmental stability	Established cell lines [REDACTED] will be used to evaluate tumor growth through non-invasive imaging.
Types of Manipulations:	NA
Source of nucleic (DNA/RNA) sequences: e.g. species	NA
Nature of nucleic acid sequences:	NA

e.g. structural gene, oncogene	
Host(s) and Vector(s):	NA
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	NA
Risk Assessment Discussion Points:	None
Training:	<ul style="list-style-type: none"> • Initial Biosafety Training • Animal Biosafety (AALAS Biosafety course certificate can be submitted in lieu of CITI training for animal work) • NIH Recombinant DNA Guidelines • Emergency and Incident Response to Biohazard Spills and Releases • OSHA Bloodborne Pathogens
Occupational Health Review (if applicable):	None
Biosafety Level: Animal Biosafety Level:	BSL 2 for invitro work, ABSL 1
IBC Vote:	Approved
3 Year Resubmission Review	
PI Name:	Asmis, Reto
Biosafety Protocol Number:	B26-W-001
Biosafety Protocol Title:	<i>Monocytic Monoamine Oxidase A in Adipose Tissue Inflammation and the Onset of Obesity</i>
Project Overview:	TBD
Applicable NIH Guidelines:	TBD
Agent Description: e.g. virulence, pathogenicity, environmental stability	NA
Types of Manipulations:	NA
Source of nucleic (DNA/RNA) sequences: e.g. species	NA
Nature of nucleic acid sequences:	NA

e.g. structural gene, oncogene	
Host(s) and Vector(s):	NA
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	NA
Risk Assessment Discussion Points:	TBD
Training:	<ul style="list-style-type: none"> • Initial Biosafety Training • Animal Biosafety (AALAS Biosafety course certificate can be submitted in lieu of CITI training for animal work) • NIH Recombinant DNA Guidelines • Emergency and Incident Response to Biohazard Spills and Releases • OSHA Bloodborne Pathogens
Occupational Health Review (if applicable):	TBD
Biosafety Level: Animal Biosafety Level:	TBD
IBC Vote:	Tabled
3 Year Resubmission Review	
PI Name:	Voorhees, Peter
Biosafety Protocol Number:	B26-CT-C-001
Biosafety Protocol Title:	Janssen 68284528MMY2003: A Phase 2, Multicohort Open-Label Study of JNJ-68284528, a Chimeric Antigen Receptor T cell (CAR-T) Therapy Directed Against BCMA in Subjects with Multiple Myeloma (CARTITUDE-2) (ClinicalTrials.gov Identifier: NCT04133636)
Project Overview:	This is a Phase 2, multicohort, open-label, multicenter study to determine whether treatment with cilta-cel (alone or with other treatment regimens) results in ██████████ in adult subjects with multiple myeloma (MM). The objective of this study is to determine the safety and efficacy of cilta-cel in various MM treatment settings
Applicable NIH Guidelines:	Section III-C-I
Agent Description: e.g. virulence, pathogenicity, environmental stability	Patient T-Cells ██████████ utilizing a ██████████. The target antigen of the CAR is BCMA which is expressed on late-stage B Cells, malignant multiple myeloma B-lineage cells and malignant plasma cells.
Types of Manipulations:	Manipulations performed by the drug manufacturer
Source of nucleic (DNA/RNA) sequences: e.g. species	NA

Nature of nucleic acid sequences: e.g. structural gene, oncogene	[REDACTED]
Host(s) and Vector(s):	Host: [REDACTED] Vector: [REDACTED]
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	Anti-BCMA
Risk Assessment Discussion Points:	None
Training:	Training provided by the sponsor
Occupational Health Review (if applicable):	None
Biosafety Level: Animal Biosafety Level:	BSL 2
IBC Vote:	Approved
Modification for Review	
PI Name:	Zhang, Wei
Biosafety Protocol Number:	B26-W-012
Biosafety Protocol Title:	Expressing [REDACTED]
Summary of Changes	Establishing expression of [REDACTED] in 3 new cell lines using a [REDACTED] system.
Risk Assessment Discussion Points:	EHS/IBC Admin will meet with research team and ARP to discuss appropriate practices for signage.
Biosafety Level: Animal Biosafety Level:	BSL 2 for lab work, ABSL-2 for 72 hours following injection, then lowered to ABSL 1
IBC Vote:	Approved
Other	
New Business:	Successful site visit with AAALAC. IBC Admin, EH&S and IACUC have several things to follow up on following the survey.
Review of Incidents:	None
Lab Assessments Update:	NA
IBC Training	NA
Public Comments	None
Adjournment	Meeting Adjourned at 1:27